REMARKS

This Preliminary Amendment accompanies a Request for Continued Examination.

Applicants have amended claim 1 to include features from presently-canceled claims 9 and 11. Claims 1-8, 10 and 12-15 are presented for further examination.

Claim Rejections Under 35 U.S.C. §§ 102 and 103

The Office action rejected claims 1-15 under 35 U.S.C §§ 102(b) and 103 as unpatentable over U.S. Patent No. 6,103,117 (Shimagaki et al.). Applicants respectfully disagree with the conclusion of unpatentability, particularly in light of the amendments to claim 1.

As an initial matter, Applicants disagree with the Office action's "claim interpretation," which suggests, *inter alia*, that the Examiner is not giving due consideration to functional language in the claims. *See* Office action at p. 2. Generally speaking, Applicants are given discretion to choose the manner in which to claim their inventions. As the MPEP states, "Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought." MPEP § 2173.01. The MPEP goes on to reiterate that "[t]here is nothing inherently wrong with defining some part of an invention in functional terms" and a "functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." MPEP § 2173.05(g).

The permselective separation membrane according to claim 1 includes the following features:[1]

Feature (1)

(a) the permselective separation membrane is made mainly of a polysulfone-based polymer and polyvinyl pyrrolidone;

[1] Applicants have parsed claim 1 into these three "features" solely for ease of reference.

Feature (2)

a ratio [D]/[C] between the polyvinyl pyrrolidone content [D] in the uppermost layer of a surface on non-blood contacting side and the polyvinyl pyrrolidone content [C] in the uppermost layer of a surface on blood contacting side is 1.1 or higher, wherein the polyvinyl pyrrolidone content [D] in the uppermost layer of a surface on the blood contacting side of the permselective separation membrane is from 20 to 40% by weight and wherein the polyvinyl pyrrolidone content [C] in the surface on non-blood contacting side of the permselective separation membrane is from 25 to 50% by weight;

Feature (3)

(b) when bovine blood at a temperature of 37°C having hematocrit value of 30%, containing 6 to 7 g/dl of total proteins and sodium citrate added thereto is flowed through a module comprising the permselective separation membrane packed therein at a flow rate of 200 ml/min. and a filtration rate of 20 ml/min.,
(i) a sieving coefficient of albumin [A] becomes not less than 0.01 and not more than 0.1 after 15 minutes; and
(ii) a sieving coefficient of albumin [B] becomes not less than 0.005 and less than 0.04 after 2 hours.

The Shimagaki et al. patent differs from claim 1 in that it fails to disclose at least features (2) and (3).

With respect to feature (2), the Office action alleges that the Shimagaki et al patent discloses a D/C ratio of 1.1 or higher and a PVP content of about 33%. Applicants disagree that such a disclosure is made in the Shimagaki et al. patent. Moreover, the Office action fails to indicate whether the "content of about 33%" refers to the content in the inner surface, the content in the outer surface, the content in the uppermost layer or the content in a layer near the surface.

In the case where PVP content of about 33% refers to the content in the uppermost layer of the inner surface, it is not described or suggested in the Shimagaki et al. patent that the hollow fiber membranes satisfy feature (2) because there is no disclosure of the PVP content in the uppermost layer of the outer surface. When a calculation is done based on the description in Examples of the Shimagaki et al. patent, the proportion of PVP to polysulfone-based polymer is as high as 50% (Examples 1, 2, 4, 7, 8, and 9), 67% (Example 3) and 47% (Examples 5 and 6). Moreover, the aqueous solution of amide-based solvent used as an internal liquid in the Shimagaki et al. patent is, by weight, 65% amide-based solvent (Examples 1, 2, 3 and 8). 70% amide-based solvent (Examples 4 and 5), 63% amide-based solvent (Example 6) and 60% amide-based solvent (Examples 7 and 9). Thus, the hollow fiber membranes disclosed in the Shimagaki et al. patent cannot satisfy the claim feature of "the [D]/[C] ratio of 1.1 or higher."

As explained in the Specification (*e.g.*, ¶[0036]), when the ratio [D]/[C] is 1.1 or higher, "(i) a sieving coefficient of albumin [A] becomes not less than 0.01 and not more than 0.1 after 15 minutes; and (ii) a sieving coefficient of albumin [B] becomes not less than 0.005 and less than 0.04 after 2 hours." Because claim feature (2) is not met, the hollow fiber membranes of the Shimagaki et al. patent cannot satisfy claim feature (3).

By satisfying features (2) and (3) simultaneously, the invention of claim 1 results in the unexpected advantage that the removal of a1-microglobulin (having a molecular weight of 33,000)—which is a uremic toxin—is enabled, while the leakage of albumin (having a molecular weight of 66,000)—which is a useful protein—is suppressed within an acceptable range.

For these reasons, the Applicants respectfully submit that claim 1 is not anticipated or rendered obvious by the Shimagaki et al. patent. Dependent claims 2-8, 10 and 12-15 recite additional features and are independently patentable.

Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The Request for Continued Examination Fee of $810.00 and two-month extension of time fee of $490.00 is being over the EFS by way of deposit account authorization. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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